510(k) Summary

DATE PREPARED

Thursday, April 30, 2009

SUBMITTER

MAY 11 2009

Aaron Hendershott, RAC
Director of Regulatory Affairs
McMerlin Dental Products, LP
1610 W. Polo Road
Grand Prairie, TX 75052
Telephone: 972.602.3746

Device Name

Common name: Hydrogel Wound Dressing

Trade names: SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel

Classification name: This device is unclassified under 21CFR Parts 862-892.

Predicate Devices

Table 2: Predicate Device General Information

510(k) Number	Proprietary Name	Product Code	Manufacturer	Classification Panel
K902345	Carrington Wound Dressing	FRO	Carrington Laboratories, Inc.	General & Plastic Surgery
K915002	Carrasyn Hydrogel Wound Dressing [Carragauze PADS]	MGQ	Carrington Laboratories, Inc.	General & Plastic Surgery
K944427	Carrasyn FDG	MGQ	Carrington Laboratories	General & Plastic Surgery
K951417	Carrasyn Hydrogel Wound Dressing [Carragauze FDG Pads]	MGQ	Carrington Laboratories	General & Plastic Surgery
K961758	Carrasyn Hydrogel Wound Dressing, et al	MGQ	Carrington Laboratories	General & Plastic Surgery

Device Description

SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel is a clear, viscous hydrogel wound dressing composed entirely of all-natural, food-grade, safe ingredients, including an all-natural preservative system. It is safe if swallowed, is designed to be physiologically compatible with both intact and compromised tissues of the skin, and will manage the pain associated with all types of injuries to the skin.

The gel's primary mode of action for pain relief is that it adheres to the wound surface, conforms to the contours of the wound, and protects the wound from contamination and irritation by forming a protective barrier that is similar to dermal tissues. It also creates and maintains a moist wound environment, which is necessary for optimal healing. SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel has been designed to be physiologically compatible with both intact and compromised tissues of the skin: the pH and osmotic pressure of the gel have been adjusted to be compatible with injured tissues.

SockIt!® Dermal Wound Gel and McMerlin® Dermal Wound Gel are exactly the same in every aspect; the same device has two different trade names.

Intended Use

The indications for SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel are the same as those for the predicate devices. This product provides management of and relief of the pain associated with all types of wounds, sores, injuries and ulcers of the dermal tissue. Examples of dermal lesions include burn wounds (First & Second degree), diabetic ulcers, pressure ulcers (stages I - IV), venous stasis ulcers, radiation dermatitis, partial thickness wounds, irritation of the skin, itching, foot ulcers, post-surgical incision, surgical sites (including soft tissue graft sites), cuts and abrasions, sunburn, skin conditions associated with periostomy care, irritation and pain following laser resurfacing treatment and dermabrasion therapy, chemical peel, and tattooing procedures.

This product is appropriate for all patient populations.

Technological Characteristics

Two of the predicate devices are hydrogel wound dressings that have been freeze-dried to produce a fibrous-like material similar to a roll of cotton. This "bandage" material is placed on a dermal wound, where it re-hydrates. Two of the predicate devices are hydrogels that are hydrated at the time of manufacture. All five of these predicate hydrogels provide pain relief by coating damaged tissues and protecting them from further contamination and irritation. [Note: All five predicate devices are predicated upon Carrington Laboratories' hydrogel wound dressing (K902345) that, like SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel, is hydrated at the factory and sold in a tube as a hydrated gel.]

Rather than have the consumer re-hydrate the hydrogel "bandage" at the time of use (i.e. contact with the lesion), SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel is hydrated during manufacture and sold in a tube or bottle in the traditional hydrated gel form.

Regardless of which method is used for hydration, all of these hydrogels adhere to the wound surface, conform to the contours of the wound, and manage pain by forming a protective hydrogel barrier over the wound, similar to undamaged dermal tissue. All these hydrogel barriers manage pain by protecting the wound from contamination and irritation.

SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel is substantially equivalent in design to the five predicate devices.

Performance Standards

No performance standards are established for this product under Section 514 of the Act.

Executive Summary

Device Description

SockIt!® Dermal Wound Gel/McMerlin® Dermal Wound Gel (SI/MC) is a clear, viscous hydrogel wound dressing composed entirely of all-natural, safe ingredients, including an all-natural, food-grade preservative system. It is designed to be physiologically compatible with both intact and compromised tissues of the skin: the pH and osmotic pressure of the gel have been adjusted to be compatible with the injured tissues, e.g. blood and other bodily fluids normally found at the wound and/or lesion site. The gel is nontoxic and is safe if swallowed.

SI/MC's primary mode of action for pain relief is that it adheres to the wound surface, conforms to the contours of the wound, and protects the wound from contamination and irritation by forming a protective barrier (i.e. wound dressing) similar to the uncompromised dermal tissue. This protective barrier provides an undisturbed, moist wound environment, which is necessary for optimal healing. The gel provides a safe, nourishing environment for the delicate cells involved in the wound healing process.

Indications for Use

SI/MC is intended to manage the pain of all types of 1st of 2nd degree dermal wounds, skin sores, injuries and ulcers of the dermal tissue. Examples of dermal lesions include burn wounds (First & Second degree), diabetic ulcers, pressure ulcers (stages I - IV), venous stasis ulcers, radiation dermatitis, partial thickness wounds, irritation of the skin, itching, sunburn, foot ulcers, post-surgical incision, surgical sites (including soft tissue graft sites), cuts and abrasions, skin condition associated periostomy care, irritation and pain following laser resurfacing treatment and dermabrasion therapy, chemical peels, and tattooing procedures.

This product is appropriate for all patient populations.

Components

Table 2: Ingredient List shows the ingredients in SI/MC and their functions in the formula. All or some of these ingredients are used. This information is confidential and proprietary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 9 2009

McMerlin Dental Products, LP
% Aaron Hendershott, RAC
Director of Regulatory Affairs
1610 West Polo Road
Grand Prairie, Texas 75052

Re: K090092
Trade/Device Name: Sockit!® Dermal Wound Gel (Hydrogel Wound Dressing)
McMerlin® Dermal Wound Gel (Hydrogel Wound Dressing)
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 11, 2009
Received: May 11, 2009

Dear Mr. Hendershott:

This letter corrects our substantially equivalent letter of May 11, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

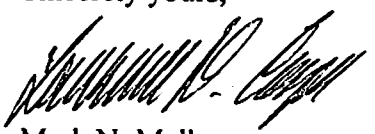
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K090092

Device Names: SockIt!® Dermal Wound Gel (Hydrogel Wound Dressing)
McMerlin® Dermal Wound Gel (Hydrogel Wound Dressing)

Indications for Use:

This product provides for the management of and relieves the pain associated with all types of dermal wounds, skin sores, injuries and ulcers of the skin. Examples include:

- All types of dermal wounds, skin sores, injuries and ulcers of the skin
- First & Second degree burns
- Pressure ulcers, stages I – IV
- Stasis ulcers
- Diabetic ulcers
- Radiation dermatitis
- Post-surgical incision
- Surgical sites, including soft tissue graft sites
- Foot ulcers
- Venous stasis ulcers
- Cuts & Abrasions
- Partial thickness wounds
- Irritation of the skin
- Itching
- Sunburn
- Skin condition associated periostomy care
- Chemical peel
- Tattooing procedures
- Irritation and pain following skin Laser resurfacing treatment
- Irritation and pain following dermabrasion therapy

Prescription Use X And/Or Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090092

Indications for Use

510(k) Number (if known): K090092

Device Names: SockIt!® Dermal Wound Gel (Hydrogel Wound Dressing)
McMerlin® Dermal Wound Gel (Hydrogel Wound Dressing)

Indications for Use:

This product provides for the management of and relieves the pain associated with all minor dermal wounds, minor skin sores, minor injuries and minor irritations of the skin. Examples include:

- Minor burns
- Minor Cuts & Abrasions
- Superficial itching
- Sunburn
- Minor burns from a chemical peel treatment
- Minor irritation and pain following tattooing procedures
- Minor irritation and pain following skin laser resurfacing treatment
- Minor irritation and pain following dermabrasion therapy

Prescription Use _____ And/Or Over-The-Counter-Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090092